# EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

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ABBOTT DIABETES CARE, INC., : Civil Action
:
Plaintiff, :
:
v. :
:
DEXCOM, INC., :
:
Defendant. : No. 05-590-GMS

- - -

Wilmington, Delaware
Thursday, February 23, 2006
11:00 a.m.

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

MARY B. GRAHAM, ESQ.
Morris, Nichols, Arsht & Tunnell
-and-
JAMES F. HURST, ESQ.
Winston & Strawn
(Chicago, Illinois)

Counsel for Plaintiff

JOHN W. SHAW, ESQ., and
CHAD STOVER, ESQ.
Young Conaway Stargatt & Taylor LLP
-and-
DAVID C. DOYLE, ESQ.
Morrison & Foerster LLP
(San Diego, California)

Counsel for Defendant



THE COURT: Please be seated. Let's start out with introductions, if we could. Counsel for plaintiff.

MS. GRAHAM: Good morning, Your Honor. Mary Graham, on behalf of Abbott. And with me this morning is James Hurst from Winston & Strawn in Chicago. He will be addressing the Court today.

THE COURT: Good morning.

MR. HURST: Good morning, Your Honor.

THE COURT: Mr. Shaw.

MR. SHAW: Good morning, Your Honor. John Shaw at Young Conaway for DexCom. With me is David Doyle from Morrison & Foerster in San Diego, and Chad Stover from my office.

(Counsel respond "Good morning.")

THE COURT: Good morning. You may be seated.

The Court wants to first make an inquiry as to whether certain things it has read in the so-called joint status report are accurate. I am at Page 9, under the heading Discovery. I see the sentence, second sentence, attributed to Abbott, that DexCom declined to discuss or propose a schedule until the Court ruled on its motion to dismiss.

I would like to know if that is correct.

MR. HURST: That is correct, Your Honor.

THE COURT: Is that correct, counsel?



MR. DOYLE: It is correct in the following sense.

THE COURT: I want to know if it is correct or not.

MR. DOYLE: We were agreeable to setting the general time frame. Then we thought, if Your Honor wanted to go forward, that Your Honor probably would want to fill in the other dates.

THE COURT: Is it correct or not, counsel?

MR. DOYLE: It is, Your Honor.

THE COURT: I see, then, this statement attributable to DexCom, at the same page, under the heading DexCom's Statement:

DexCom believes that the parties should not discuss specific dates or schedules until this Court rules on the pending motion to dismiss Abbott's complaint.

Is that an accurate statement?

MR. DOYLE: It is, Your Honor.

THE COURT: It is extraordinary. Please be seated.

This is a formal session of Court, and it has been convened in large part to remind you, particularly counsel for DexCom, where you are. This is a United States District Court. I am a United States Judge. I do not issue requests. I issue orders.



Did you misapprehend, counsel, that the notice of scheduling that you got in this case was a request? Counsel, that requires an answer.

MR. DOYLE: I just want to be sure --

THE COURT: I will read it for you. You should have all -- you may not have it with you. But I have a form. I don't have the actual notice in hand that was electronically filed. But it reads in part:

It is hereby ordered, in bold, all caps, that pursuant to Rule 16, Federal Rules of Civil Procedure, and Local Rule 16.2(b), a status and scheduling conference in the above-referenced matter has been set at the United States Courthouse, 844 King Street, Room 4325, Wilmington, Delaware. Counsel with primary responsibility for this case shall appear and be prepared to address any pending motions in preparation for the conference. Counsel are directed to confer with respect to all agenda items listed below.

And there are a number of them listed.

This order of the Court triggers, automatically, certain rules, known as the Federal Rules of Civil Procedure. Specifically, Rule 16 and Rule 26(f). Yet you sit here before me, counsel, admitting, having done so in writing previously, that you declined to follow an order of this Court.

Can you explain yourself? Please approach the

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podium and do so.
MR. DOYLE: Yes, Your Honor. Our problem is the following.
We don't have the two key, we don't have the two key elements --
THE COURT: Stand up straight, counsel. Don't lean on that podium.
MR. DOYLE: We don't have the two key elements necessary to set a schedule in a patent case here. First, there is not an accused product.
THE COURT: In your view -- and I am not going to give you an opportunity, as you attempted here in this joint status report, to argue your position on the motion to dismiss, positions of which I am now aware. Quite frankly, counsel, I view this, in addition to being boldly recalcitrant and disrespectful of this Court's process, not of this Judge as a human being, but of this office, the office that I hold, the black robe that I wear, that I wear, counsel, not you, regardless of what you believe may be the case, this Court has ordered you to appear --
Mr. Shaw, sit down.
I have had a chance to review the summary of the arguments in the motions. Quite frankly, I don't think you have a winning position. But I have not finally determined whether you do or you do not.

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You are not the first party who has come before this Court having filed a motion to dismiss wanting to jump ahead in the queue, to get your matter resolved ahead of everyone else. Quite frankly, that is what I believe is a part of the tactic that has been employed here.
I don't like it. I won't tolerate it. If this matter were the only one that the Court had on its docket, I would gladly -- you would know the Court's position. You would have known it well in advance of your coming here today. Maybe you would have prevailed and would not even be here today. But you have not prevailed. And consequently, you have certain obligations as an officer of this Court, having been admitted pro hac, you have responsibilities that you must attend, counsel.
So I don't want to hear from you regarding the merits, what you believe to be the merits of your position on your motion to dismiss. And I won't hear from you regarding your position on scheduling, because you forfeited that opportunity and that right to have input into what this schedule will eventually be.
You may sit.
MR. DOYLE: Yes, Your Honor.
THE COURT: We are going to go to scheduling. But for the fact that I don't want to penalize the plaintiff, who comes here in good faith today, having

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followed the orders of this Court, or attempted to, at least, I would send you all away and tell you to come back another day. But I think that would be an abuse of my discretion, quite frankly, and, quite frankly, would be unfair to the plaintiff.
I have thought about other remedies as well. I have elected not to consider them as well, including finding you in contempt.
If we could go to Tab 1 in the so-called joint status report, we will discuss the schedule.
Plaintiff has proposed that initial disclosures be completed -- I guess they have been completed. Is that correct?
MR. HURST: We have supplied our initial disclosures, Your Honor. DexCom has not.
THE COURT: When are you going to be able to do that? Do you want to address that, Mr. Shaw?
MR. SHAW: I was going to say, Your Honor, we had objected, as permitted under Rule 26(a)(1), as to doing the initial disclosures -- as far as the date, Mr. Doyle will address that. Your Honor, if I could --
THE COURT: You can step up, Mr. Shaw.
MR. SHAW: I need to apologize to Your Honor because in part the draft scheduling, joint status report is my doing. The one thing that I had wanted to make sure was

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in front of Your Honor were all the issues that could bear on scheduling. That is why I had counsel in favor of identifying the open issues.
THE COURT: I don't have a problem with identifying issues, Mr. Shaw. I have a problem with the behavior that was attendant to your position, the position that you and your colleagues took.
MR. SHAW: I understand that, Your Honor. I apologize for that.
We do have one thing that is in there on scheduling that is important. We did look at the case and think about how long it would take to get to trial. We did identify that in the portion about discovery and the length of discovery.
In terms of the relative dates that were in there, based on the trial date, once Your Honor has selected that trial date, for the most part, are not disagreeable to DexCom or even issues with DexCom.
The primary point that was important for our side to address was the trial date relative to fixing what the issues were in the case in terms of products. That is at the end, I believe, of Paragraph 9, on Page 10.
THE COURT: What is it?
MR. SHAW: Just the relative time to trial, that 24 months was the time frame that it looked like this case

would need to be prepared, and then we had looked at dates backwards from the trial date that Abbott had proposed. In other words, in terms of the scheduling dates that Abbott was proposing, if you look at those relative to the trial date, roughly, those are all fine, with one area we wanted to comment on, which was the disclosure of opinions of counsel.

But I wanted to, A, first of all, make sure I had told Your Honor how this report came to be the way it was, also to point out one of the important items that is in here is the 24 months to trial. And the reason that is in there is multi-fold, has been, the items Mr. Doyle has identified.

You have identified the outstanding items of subject matter jurisdiction.

THE COURT: We can jump ahead, and I will permit you to have input, Mr. Shaw.

The trial date is going to be October 8th of '07. So I think that will probably address concerns.

MR. SHAW: Thank you, Your Honor.

THE COURT: So, then, the question remains to DexCom, when will you be in a position to provide your initial disclosures?

MR. DOYLE: As soon -- we will prepare -- let me step up, Your Honor.



We will prepare at whatever date Your Honor directs us to. We can do that based on the information currently available to us. Again, I am not trying to argue the merits of the pending motion. It is just our product is a prototype. We can answer on the basis of that prototype as submitted to the FDA. We are still right in the middle of the FDA process. There remains a material likelihood that we will be asked to modify that product.

But we can answer and will do so at Your Honor's, whenever Your Honor would like to in terms of our current prototype.

THE COURT: Mr. Hurst.

MR. HURST: I guess I would prefer to see the initial disclosures earlier rather than later. If I can address the point about the prototype, Your Honor.

THE COURT: Sure.

MR. HURST: I don't know if you do want to hear about the merits of the motion. I understand you don't.

THE COURT: I don't.

MR. HURST: I have --

THE COURT: I would love to if I had time to prepare. By that I mean have written briefs. I haven't had time to do that. I have other things to do.

MR. HURST: On the strict issue of the initial disclosures, we would prefer to see them sooner rather than



later in order to keep with the schedule we had proposed.

THE COURT: For sooner, counsel, what can you handle?

MR. DOYLE: Two weeks, Your Honor?

THE COURT: Acceptable?

MR. HURST: That is fine, Your Honor.

THE COURT: What date is that, Ms. Walker?

MS. WALKER: March 14th.

THE COURT: March 14th is two weeks by our calculation. That would be the date for the provision of initial disclosures by DexCom.

Now, the reliance upon the advice of counsel -- you see, as annoyed as I am, it occurred to me before I came out and it occurs to me of course again, it is really not in the best interests of anyone to have a schedule that is unrealistic. This is why we have a 26(f).

So, per force, we are going to need to have input from both sides. In the main, my inclination is to decidedly to accept the schedule insofar as we are able that the plaintiff has proposed.

So here we have plaintiff proposing that the reliance upon advice of counsel be completed by July the 13th, at least disclosure of the decision. I gather you are talking about the production of opinions?

MR. HURST: Yes, Your Honor.



MR. DOYLE: Your Honor, that was the only aspect of the schedule that I found problematic, because as I know Your Honor appreciates, it is such a key strategic decision in the case, I would prefer that that be, if possible, after the claim construction hearing. Other than that, the other dates seem to make sense.

THE COURT: Mr. Hurst.

MR. HURST: The reason I think it needs to be earlier, Your Honor, is because if they do decide to rely on counsel's advice, we are going to need to take discovery on that. We would rather have it earlier rather than later so we are not re-plowing ground that we have already been over. So July 13 seems to make sense to me.

THE COURT: Do you want to reply to that?

MR. DOYLE: Yes. Because the only discovery that relates to the opinion would be lawyers.

THE COURT: And the deposition, yes.

MR. DOYLE: Yes.

THE COURT: I am inclined towards later on this, because I think counsel is correct, that we are talking about the opinion, or opinions, and the depositions of counsel.

MR. HURST: That is acceptable, Your Honor. Thank you.

THE COURT: So, counsel -- it's Mr. Doyle, is

it?

MR. DOYLE: Yes, Your Honor.

THE COURT: What do you want to propose in terms of this date?

MR. DOYLE: Yes. Looking at this schedule, if it is going to be consistent with the Court's availability, to have a Markman hearing around September 11.

THE COURT: We are going to do Markman October 24.

MR. DOYLE: If we could have till maybe the day or two before Thanksgiving, after that, whatever that day is.

THE COURT: What day is that, Ms. Walker?

MR. SHAW: Your Honor, I was going to suggest maybe two weeks after the opinion comes out, the Markman opinion.

THE COURT: That is fine.

MR. DOYLE: That would work, yes, Your Honor.

THE COURT: Typically, though not in every instance, but in most, I think the vast majority of cases I have been able to get my Markman orders, not opinions, orders out within 30 days of the hearing. The Federal Circuit hasn't jumped on me yet. They are coming, though. I hear them close on my heels.

So until I have been directed otherwise, I will



continue to do that. That makes sense.

Two weeks after the -- we are talking November 24 or somewhere around there, two weeks after that.

MS. WALKER: December 8th.

THE COURT: Ms. Graham, I am going to ask that plaintiff prepare this schedule.

MS. GRAHAM: We are happy to do that, Your Honor.

THE COURT: You got that last date then?

MS. GRAHAM: Yes.

THE COURT: So then the cutoff for joinder proposed by plaintiff and amendment of pleadings is October 2. I have some difficulty with that, counsel, that cutoff being that late in the process. You know, if you wanted to confine it -- if you are concerned about inequitable conduct or something like that, that is really what the rub is, and you want to confine the amendment and joinder to that specific area, I think that would be more acceptable and perhaps -- because the Court is going to accept the October 20 fact cutoff. But I wouldn't want to explode the schedule by adding patents and parties that late, certainly without good cause, very, very good cause.

So if you want to consider bifurcating the amendment and joinder cutoffs, you can do that. What do you want to do?



MR. HURST: Your Honor, there is some likelihood that we will add patents to this case. Although I don't think I need as far out to October 2nd. An earlier date would be acceptable to Abbott. I would even suggest as early as July 15th.

THE COURT: Well, I am sure the defendant is not going to have a problem with that, it being sooner rather than later. You might have a problem with the point that was made about adding patents.

MR. DOYLE: Yes, Your Honor. Again, that has been a big part of our concern, because we know they have got more patents coming.

THE COURT: I am sure that is part of the reason that you moved in the manner that you have.

MR. DOYLE: Yes, Your Honor.

THE COURT: July 15 then it is.

MS. WALKER: July 14.

THE COURT: July 14, okay. Of course, counsel, lest there be any question -- incredibly enough, this came up in a case -- of course, you can move after the cutoff for good cause to amend and join. I was just astounded when I had it argued by very seasoned counsel not long ago that they didn't understand that. They thought the cutoff was the cutoff. How can that be?

Okay. July 14th.



All right. Then, plaintiff has proposed the following, in terms of the preparation, the meet-and-confer, the gearing up for the Markman process, that the initial exchange of list of disputed terms occur by the 26th of June, that the meet-and-confer take place by July 10, if not on July 10. Is that the actual date you are proposing?

MR. HURST: Yes, Your Honor.

THE COURT: On July 10.

That final joint claim charts -- and you should put in there, with a reference to the intrinsic record, that should be a part of the scheduling order. There is language around to that effect -- by July 17.

Those are the dates that plaintiff continues to propose?

MR. HURST: Yes, Your Honor.

THE COURT: I am assuming those are dates by which, having already indicated that in the main other than what has already been stated you could agree with, the dates that have been proposed by plaintiff?

MR. DOYLE: Yes, Your Honor.

THE COURT: So, then, opening claim construction briefs, July 31. Answering briefs, August 28th.

Markman, October 24, 10:00 a.m. Now, we have four patents and I have just been told that there is a possibility -- this all assumes, obviously, that the action

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survives the motion to dismiss. How many more patents are we talking about?

MR. HURST: Your Honor, we are reviewing that right now. I do not have an answer for you. I think right now there is at least a likelihood that one more patent will be added. But I don't have a specific number for you.

THE COURT: How do counsel characterize this particular technology in terms of complexity? What are we dealing with in terms of complexities?

MR. HURST: We are dealing with glucose monitors. It's probably about, similar in complexity to your average pharmaceutical case. It has to do with remote glucose monitoring.

Right now patients, the standard of care is that, someone who is a diabetic, they have to prick their finger several times a day to measure their glucose levels. The invention at issue was accomplished in the early nineties, mid-nineties by our inventors.

What it does is creates a remote monitoring system, so you put an electrochemical sensor within the body and you have a battery on top of it, a radio transmitter. And you essentially carry around something that looks like a cell phone. So it is pretty much constant, periodic, every five minutes or so, measuring your glucose levels, rather than several times a day.

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That is the technology. I would have to say the technology itself is somewhat complex, because electrochemical sensors are pretty complex. And you are talking about combining different fields.

THE COURT: Mr. Doyle.

MR. DOYLE: That latter point would be the point I would make, Your Honor. More complex than the typical pharmaceutical case, because this is a combination of an electronics case and biologics case. So you have got combinations of two complex areas and the interface between two complex areas.

THE COURT: All right. Fortunately, Ms. Nerozzi is a biochemist and my other clerk is an electrical engineer. So it helps.

We will set aside a day for Markman. Does that seem reasonable under the circumstances?

MR. DOYLE: Yes.

MR. HURST: That seems fine, Your Honor.

THE COURT: So as I have indicated, close of fact discovery, the date proposed is acceptable to the Court.

I want to hear now from both sides as to whether -- clearly the plaintiff believes this is realistic. I want to hear from DexCom on it.

MR. DOYLE: I would suggest that we perhaps move

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it -- it appears that the schedule was put together by Abbott with the idea that discovery cutoff would follow one month after the claim construction. That seems like a logical spot for it. So I am wondering, with the change to October 24th for the claim construction hearing, a decision by November 24th, maybe we make fact discovery close at the end of the year, around December 31.

THE COURT: The only concern I have about that, and not having the Markman hearing at least closer, perhaps, to the completion of fact discovery, is I don't want to have a re-do. I don't want to have new information discovered that may be pertinent to Markman and have to come back again and re-do that. That is my thinking on how I approach those things. I am willing to flex.

What is your view?

MR. HURST: Perhaps not until the end of the year. Maybe another month, to November 20th.

THE COURT: Okay.

MR. DOYLE: Yes, Your Honor.

THE COURT: We will do that, then.

MS. GRAHAM: If I might just mention something, Your Honor, so people on both, both my co-counsel and the other co-counsel are thinking about it. The thing for everyone to keep in mind here is then the sequencing and the date. I always back up from the date we are going to have

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the summary judgment briefing and giving Your Honor enough time. So everybody needs to realize that we may be looking at jumping up the expert dates a little bit, and then to have the summary judgment briefing completed in time.

THE COURT: I am prepared to have counsel meet and confer and discuss this part of the schedule, in terms of the expert reports and the cutoff of expert discovery, and make a proposal to the Court, rather than trying to flesh that out at the moment. It may be that you want some time to talk about it.

MS. GRAHAM: We can do that. I think we would be able to work it out.

MR. DOYLE: Now that we know the big dates, that should be pretty easy to do.

THE COURT: If you submit something in terms of the -- let me give you this date. March 16 at 10:00 o'clock for the TC, the teleconference on summary judgment. Then you can work out -- I think you appropriately set an abbreviated briefing schedule, letter briefing schedule for those letters requesting permission.

MR. SHAW: Your Honor, you would like the letters to be finished a week before that teleconference.

THE COURT: Exactly, Mr. Shaw. Thank you.

So, then, I would set the cutoff for filing issue or case-dispositive motions that are permitted to be

filed at April 2, or two weeks from the Court's decision, assuming -- should the decision come after the teleconference, whichever is later. You brief under the Local Rule, rather than the type of schedule you have suggested. I think the Local Rule accommodates. It may be that the Local Rule may change. It may expand the briefing schedule in patent cases, I don't know.

The District Court Advisory Committee is in the process of re-doing our Local Rules. So we will see what we come up with.

I am going to eliminate the Daubert teleconference. We have just not been using it. Counsel have uniformly, almost, suggested that -- we have them in a number of the older schedules that are running around. We are taking them off the schedule. What we are doing is taking care of Daubert matters at the PTC, the pretrial conference. The lag between, the gap between my pretrial conference and the start of trial provides sufficient time, should we need it, to convene a hearing on Daubert, an evidentiary hearing, should one be needed.

So we have just not been doing Daubert on the phone.

So the briefing schedule, the type of briefing schedule that you have proposed is fine with me, as long as whatever you propose at the end of the day is consistent



with this. It doesn't have to be exactly these dates.

Your joint proposed pretrial order will be due August 13, '07, by the close of business. There is a form of order on the Court's website. Please download it and follow it.

The pretrial conference will be the 10th day of September at 10:00 o'clock. We will likely convene an informal session of the Court. It will be a conference. But we will probably do it in here, and I will sit down there, just so we will have space.

Trial, as I have told you, October 9. Given the number of patents, it strikes the Court in its experience that ten days is not an unreasonable number of days to allocate to trial.

Let me say a quick word about discovery disputes, which, of course, given the fact that we only have one Magistrate Judge, who, because of her incredible scheduling and talents, not that she doesn't have talents in these areas as well, but in acting as a neutral in mediation and other types of ADR, she spends a lot of time doing that, so she doesn't do that much of the District Court's pretrial work, if any. I will speak for me. I handle my own discovery disputes to a point.

The way you bring them up is having one or both parties call. We will get a date for a teleconference. 48



hours in advance of that date, you will be told I must have a letter of no more than two pages, and it must be nonargumentative, nonargumentative. You can outline for me what the nature of the issues are. And we will get on the phone and talk about it. If I am feeling uncomfortable about ruling because I either need to think a little more about it and maybe want to read some cases you have cited to me during the conference or whatever, I will do that. If I am feeling even more uncomfortable and feel that maybe I would benefit from some letter briefing, I will let you do that.

Those briefs usually end up being anywhere from two to five pages.

If I am really uncomfortable and feel motions practice is needed, that will be allowed.

I expect and require that counsel are the main settlers of disputes along these lines. I expect them to occur. Especially in complex, high-stakes civil litigation, they are going to occur. I know that. Sometimes it's just going to be necessary to involve the Court.

I let you do that with me three times. After that, then I am going to send you to a special master. Of course, your clients will have to pay for that service.

I think we have covered all of the, to the extent that we need to today, all of the important dates in



the life of this case. Counsel are going to be left to go over some additional things.

It is your turn now to talk to me about whatever else it is that is on your minds.

Mr. Hurst.

MR. HURST: There is one issue we would like to address, Your Honor.

As we mentioned in the joint status report, Abbott is considering filing a motion for a preliminary injunction to avoid the launch of DexCom's product, which we believe to be an infringing product.

We served a deposition notice on February 2nd for a 30(b)(6) witness to get the details of that product. We want authenticated, admissible, definitive proof of infringement so we can support our motion for a preliminary injunction to the extent the client decides to go forward, which we expect it to.

We noticed it up for February 21st. Because of the positions that DexCom was taking at the time, they declined to produce anyone. And so I am worried that their launch is coming in the next few weeks. I want to avoid the mad scramble that will occur if that happens when I have to rush to the Court looking for discovery, filing emergency motions, because this is the situation we are facing.

DexCom got approval in May of '05 for an

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expedited application for its product to be approved by the FDA. The FDA targets 300 days for making decisions on their expedited applications. Your Honor, 300 days brings us to the middle of March of '06, when the FDA, if they meet their own stated goals, which they are trying to do 70 percent of the time, they could be approving DexCom's product for launch within weeks.

What makes us more nervous about this happening in the next couple of weeks is we have asked counsel for DexCom for an assurance that they won't launch before March 28th, let's say, so we would have a little time. They declined to give us that assurance. Moreover, our sales force right now are being contacted by DexCom. They are recruiting our sales force.

We got to believe that they know now that launch is imminent. And I understand counsel said it is uncertain and he doesn't know for sure and nothing is sure with the FDA. All indications are, Your Honor, that it is happening very, very soon.

So I would like to get a 30(b)(6) deposition so I am in a position to file my papers as soon as possible so if Your Honor -- I am requesting a 30(b)(6) deposition on the details of DexCom's product within the next ten days, if that is possible.

THE COURT: Mr. Doyle.

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MR. DOYLE: First, let me discuss the FDA process and where we stand in that, Your Honor.

If only the FDA were as scrupulous as this Court is in adhering to its schedule. It's just not the case.

Our FDA situation is essentially identical to what it was when this case was filed on August 11. We have had a lot more interaction, but no material step has occurred yet within the FDA at this point.

The next thing that could happen would be the FDA will make a decision as to whether to refer our product to what's called panel review or not panel review. That has not happened.

If it goes to panel review, then we would be lucky to have a product any time in 2006. Thus, again, the reason -- and I apologize, Your Honor, I did not mean any offense to the Court -- it just seemed impossible to me, given, still, the significant likelihood that we will go to panel review, that I could honestly state to your Court when we would be prepared to make disclosures and to agree to a schedule. That's why we took the step that we did.

If we are fortunate, and we avoid panel review, then sometime within a month or two, my understanding is, we will get hopefully what is called an approvable letter. Once DexCom has an approvable letter, there is then another one or two-month period in which DexCom has to engage in

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extensive discussion, negotiation, with the FDA, to work on product labeling, all kinds of other details involved with actually launching a product, and get all that approved by the FDA.

Only then would there be an approved letter, and then, of course, despite the fact that DexCom is optimistic -- and, yes, they are trying to do some hiring in the process of getting ready to hopefully have a product some day. The idea that we should spend our time or Abbott should spend their time right now taking a 30(b)(6) deposition, until there is an approvable letter -- there will be plenty of time for that once there is an approvable letter. An approvable letter is a material event that, DexCom is a public company, will disclose, so Mr. Hurst and Abbott will know about it as soon as DexCom knows about it.

So I would, given that process and where we are in that process, I think the concern is really a bit of a -- I would suggest, Your Honor, it is not completely genuine in that Abbott knows this FDA process better than DexCom. And I think again, just as they filed the case on August 11, way before there was any realistic possibility we would have a product, that now they want to start discovery way before there is any need to do so, especially with the motion pending.

Again, the approvable letter will lead to at

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least the 30-day period that counsel is asking for. That will be disclosed.

THE COURT: So there's at least 30 days between the issuance of the approvable letter and the --

MR. DOYLE: Exactly, Your Honor. That is best case, if everything goes well and we get a lot of attention from the FDA. And the FDA is a busy place, so we can't really count on that.

THE COURT: Let's hear from Mr. Hurst.

MR. HURST: Your Honor, what I didn't hear is any prejudice to us having a 30(b)(6) deposition. Discovery is now open. It's been open since February 2nd. I properly noticed up a 30(b)(6) deposition for February 21st, which they just declined to come to the deposition. And I guess I would like to proceed with discovery.

In terms of the timing of things, two things that Mr. Doyle said. He said there is a possibility that the FDA is going to order a panel review, which will delay things a lot. Abbott is in front of the FDA on a similar product right now. We have already heard from the FDA, informally, that a panel review will not be necessary for the kind of labeling that DexCom is asking for. I imagine they got the same indication from the FDA.

Second, the timing between an approvable letter and an actual launch, I am not a regulatory expert, I have

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talked to my regulatory folks, they say, yes, sometimes it takes some time so you will have notice. But sometimes, if you work really hard with the FDA, you can move it so that the actual launch occurs very near the time of the approvable letter.

All I am trying to avoid is an absolute, mad crunch. There is really no prejudice to DexCom for me to go forward and take a single-day 30(b)(6) deposition on the details of their product.

THE COURT: I am going to order the deposition. I did not hear from Mr. Doyle, as you correctly pointed out, that there would be any prejudice to DexCom in participating in the 30(b)(6). Having heard none, I will order that the deposition occur. What was the time frame?

MR. HURST: I asked for the deposition within the next ten days.

THE COURT: Counsel can meet and talk about this.

MR. DOYLE: Right. I will have to find out --

THE COURT: You have to find a representative. But it must be within a reasonable period of time, and must comport with the spirit of what counsel is requesting, a sooner rather than later, as we bandied that term about, deposition would be required.

MR. DOYLE: Yes. Do we also have an

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understanding that the subject matter of this deposition is as stated to Your Honor? Because it is very different than what had been stated to us before. What counsel has been stating to us is that he wanted to do discovery, or Abbott through Mr. Hurst has been stating to us, wanted to do discovery about our FDA process and where we were in that. And Your Honor had already declined to allow that discovery.

THE COURT: I did. Let's pin this down.

MR. HURST: The deposition notice has two parts, Your Honor. Topic No. 1 was for each accused product describe in detail the structure, function, use and operation of such products and their component parts, including the materials used to make the component parts and the dimensions of those parts. That was Part 1.

Part 2 related to the discovery on the status of their FDA approval efforts. I did not understand you to deny our motion for discovery on that but rather to delay it. We asked to have it heard earlier rather than later, but you declined that request.

THE COURT: I think your request this morning was tailored to --

MR. HURST: No. 1, it was.

THE COURT: We will confine it to that.

MR. HURST: Thank you, Your Honor.

MR. DOYLE: Thank you, Your Honor.

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THE COURT: Okay. From DexCom, does DexCom have any matters it wishes to discuss beyond those we have talked about? Again, I think there is a motion to stay as well. One of the patents has been put in for reexam.

MR. DOYLE: All four have been put in. If the fifth patent is the most recently issued patent by the Patent and Trademark Office, that is in the same family as some of the asserted patents, then we will be seeking reexamination of that patent as well, Your Honor, based on our review.

THE COURT: When did they go in?

MR. DOYLE: Our applications, one was filed in late December, and the other was in early January.

THE COURT: Okay.

MR. HURST: Your Honor, Ms. Graham pointed out a concern that I hadn't anticipated when we were talking about the scope of the deposition.

The Topic No. 2 actually does address the timing of DexCom's likely approval and their current communications with the FDA. What Ms. Graham pointed out to me, which I hadn't --

THE COURT: We will include Topic 2 in the 30(b)(6).

MR. HURST: Thank you, Your Honor.

MR. DOYLE: Your Honor, about that, as I have

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described, we are a public company. Any material event that occurs, we have to disclose it immediately. So again, it seems to us to have them -- what they want to do is they want to ask us to speculate as counsel here has speculated, well, Abbott thinks that maybe the FDA is thinking because they have got an informal suggestion, I just don't understand the point of that, other than to address Abbott's angst about something where there need be no angst, given the FDA's process and what everybody knows about it, just trying to allow our company to focus on getting the FDA approval rather than spend time in deposition.

THE COURT: Certainly.

MR. HURST: Your Honor, I just want to know the subject matter of the communications. The FDA has a guidance that says they communicate with the applicants every 30 days. In practice, they do do that. Right now, DexCom knows whether there is any major hurdles as to whether or not they are going to get approved. In order to prepare for a possible motion for preliminary injunction, we would like to know the timing of that motion. It is not any burden on DexCom.

THE COURT: I will permit it. Anything else? Counsel, we are adjourned.

(Conference concluded at 11:50 a.m.)

Reporter: Kevin Maurer

## D

## Q



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## S

# EXHIBIT 2

**EXHIBIT 2**

**TRANSCRIPT OF CONFERENCE CALL WITH INVESTORS FROM FEBRUARY 27, 2006**

Today's conference is being recorded. At this time all participants are in a listen only mode. Following today's presentation, we'll conduct a question and answer session. Instructions will be given at that time for you to queue up for your questions. Now at this time, I would like to turn the conference over to Andrew Rasdal, Chief Executive Officer. Mr. Rasdal, please go ahead.

**MR. RASDAL:**

Hi and good afternoon and thanks for joining us. I'll let Steve Kempfer, CFO, start out with some initial remarks.

**MR. KEMPFER:**

Hello everyone and thank you for joining the call. I just would like to repeat the Safe Harbor statement. We will be making forward looking statements about our business, regulatory areas and other areas of the company, so please refer to our 10K as well as all of our other SEC filings for a full discussion of the Risk factors. Thanks and I will turn it back to Andy now.

**MR. RASDAL:**

Great. What I would like to run through today here in terms of an agenda is first talk about our short-term sensor program, talk about the regulatory status, our clinical, technical development progress and our preparedness for any potential commercialization, I would like to spend a little time updating on the long-term program, provide an overview of our litigation and intellectual property status. I'll then turn it back over to Steve and let him go into more detail through the financial results and then wrap up with a few closing comments and then open up for questions. So, at this point, I would like to start on the short-term update. At this time we have nothing material regarding the umm, from the FDA regarding our PMA report at this time. We still hope for a decision from the FDA regarding the approvability of our PMA for the STS by early Q2, as we previously guided. Although we cannot predict the FDA's decisions, we remain very optimistic. Also, on a semi-regulatory front, our request for a waiver for our STS to transmit in the mix band frequency was granted by the FCC. We're thankful for the FCC's consideration and decision on the matter. We'd also like to take time just to thank the folks. We're very appreciative of the effort by clinicians and patient advocacy groups to help educate the FCC on the potential impact of continuous glucose monitoring may have on people with diabetes.

From a clinical and technical standpoint, we had an article authored by our clinical investigators from our pivotal clinical study for STS which was pure reviewed published in the January, 2006 edition of diabetes care publication of the American Diabetes Association. The article provides the full results from the study and highlights the potential clinical and economic impacts of continuous glucose monitoring. Obviously, we're all excited to have the article this early, having a peer review article citing clinical outcomes related to continuous glucose monitoring will be very helpful to ours and others future

regulatory reimbursement efforts as well as, ultimately, providing our field force an important educational tool.

We've also submitted data from our 7-day trial to be considered for publication and presentation at the annual scientific session for both the ACE meeting and the American Diabetes annual meeting for 2006. We're still on track and intend to submit a PMA supplement for approval after an FDA approval for our PMA for the STS's received. Since we completed our 86 patient 21-day study for the 7 day STS last July, we continue to make considerable technical progress we believe improves the performance and user ability of the product. We may conduct a short small registry to incorporate these improvements into the PMA submission, when and if we submit that.

Based on conversations with patients and physicians in our ongoing trials, we continue to believe a 7-day short term sensor may offer an even higher level of convenience and disease management and further differentiation for DexCom. We're excited the acceptance of the 7-day sensor is very attractive to the company from a profitability perspective as we do not expect the 7-day STS to cost much more to manufacture but do expect some pricing premium over the 3-day short term sensor.

We had talked on our last call that we had initiated some feasibility studies to further explore what may be required for a replacement claim labeling from the FDA. Towards the end of last year we had completed, we enrolled 35 patients in five feasibility studies at 3 US centers to evaluate the study design and sensor performance related to seeking replacement claim from the FDA. We believe we now have a better understanding of the sensor performance and the studies that are required for replacement labeling. However, there is still no clear guidelines from the FDA for replacement claim nor is there any clear predicate to study or device. However, we intend to file an IDE with the FDA for a replacement claim to start a study sometime after we have received a decision regarding approval of our current STS PMA.

We are also currently enrolling a trial that allows us to collect data on or gain experience with patients using the STS continuous for a 3-month period or 90 days of consecutive use. If fully enrolled, the study could have up to 400 patients at 20 US centers. We've currently enrolled and enrolled approximately 130 patients at 7 US sites and are gaining a great wealth of both data and experience with a product having people use it for much longer periods of time.

We've continued to prepare for potential commercialization should we receive FDA approval. It's our desire to launch the STS as soon as possible if we receive approval. Back in November we hired Rod Kellogg as our vice president of sales to build our field sales and our customer service organizations. We've hired our first regional sales managers and currently are conducting interviews with potential sales representatives. We're very pleased with the quality of potential candidates that have approached us and we expect to have an initial field force in place when and if we receive FDA approval.

We've also made some significant internal progress. We've installed the infrastructure including the information technology systems required for us to receive, process, ship, field and service customer orders if we receive approval. We've continued our focus through Q4

on process development and optimization of our manufacturing to allow us to reliably scale production if and when we receive approval.

In the 4th quarter of '05 we made a significant investment in materials and supplies that would be required to build product if we received approval. We streamlined and solidified the processes for working more effective and efficient with our key partners such as AMI Semi-conductors who supplies our AZTEC to us and in Q-4 we invested in numerous trial production runs to test and to validate our manufacturing processes to make reliable products. These products are essentially all consumed in an in-vitro animal testing or human clinical studies during the same quarter to insure consistent and reliable performance in the actual situation of in vivo use.

Related to our long-term censor program we've continued to make technical progress on the program. We continue to be pleased with the new innovations especially the new biomaterials we mentioned on the last call that we made related to our materials that may improve performance. We are currently evaluating the impact of these innovations on our G-3 platform and animal studies showing extended use. We plan to fully evaluate these potential improvements as we mentioned before, potentially including human feasibility trials outside the US before enrolling any additional patients in our US IDE that is currently open.

Clearly as we continue to raise the level of performance of our STS patent form including demonstrating the ability of our short-term sensor perform reliably over longer periods of time. We also raise both the internal and external expectations for the performance of our long-term sensor program.

Related to our current litigation with Abbott, Judge Sleet, the presiding Judge in the case, held a scheduling hearing on the litigation on February 23rd. He did not and has not ruled on our motion to dismiss the case. He did set a trial date for October 2007. Thus, without any delays, it will be approximately 20 months from now when we begin arguing the case in court.

We also filed a request with the US Patent Office for the re-examination of all 4 patents cited by Abbott in their complaint. Based upon our legal counsel's analysis of these patents, we feel there is ground for re-examination of those patents. However, this no guarantee that the US Patent Office will grant our request for one or any of those for re-examination. We'd expect a decision regarding our request for re-examination in the next 90-days or less. If our request for re-examination is granted, we'll have more to say at that time about the possible outcomes and implications. In the meantime, we have filed another motion to stay the case based upon our request for re-examination.

Regardless, we refuse to be distracted from our passionate commitment to obtain approval for the short-term sensor and to make it available as soon as possible for people with diabetes who may benefit from this important new technology. With that, I would like to turn it over to our Chief Financial Officer, Steve Kempfer to comment a little more fully on the financial results from the quarter as well as the year.

**MR. KEMPFER:**

Thanks, Andy. As Andy mentioned I will go really briefly through the financial covering first the 4th quarter and then speaking about the full 2005 fiscal year.

DexCom today reported a net loss attributable to common share holders of 12.1 million for the 4th quarter of 2005 or a loss of 48 cents per share compared to a net loss of 4.6 million for the 4th quarter of 2004 or a loss of a $1.98 per share for that period. The per share numbers are not directly comparable due to the relatively low level of common share adult standing in 2004 that was prior to the conversion of a preferred stock that happened around our IPO.

Research and development expense excluding stock base compensation increased 7.7 million to 10.7 million for the 4th quarter of 2005 compared to 3.1 million for the same quarter in 2004. As we are still a development stage company, our R&D includes manufacturing, clinical and regulatory as well as development and engineering. The increase was primarily related to 6.2 million increase in our manufacturing expenses and a 1.5 million increase on the development side. Included in the manufacturing related costs were 5.7 million in higher material procurements to support our repeated use study that Andy mentioned as well as for materials received in preparation for volume production. Again, as we are a development stage company we are still expensing all of our materials.

The 5.7 million material expensing includes approximately 2 million in materials and supplies that were on hand at the end of the year as well as the recording of a 2 million dollar loss on firm purchase commitments for some electronic materials scheduled for delivery in early 2006. This purchase commitment is related to an initial quantity of some on order electronic materials that we currently do not plan on recovering in our initial sales. These costs should decline rapidly as we scale our manufacturing operations.

The 1.5 million in higher development expenses are primarily associated with increase compensation as we continue to build up R&D team and for design costs related to the design of production tooling and fixtures. Our SG&A expenses included stock base comp, increased 1.1 million to 1.5 million for the 4th quarter of 2005 compared to 440K for the 4th quarter of 2004. Increases here were in two main areas approximately 300,000 in initial sales and marking expense where we had none in 2004 and approximately 400,000 in public company expenses, insurance, legal, board expenses, accounting, Sarbanes-Oxley, that sort of thing.

Stock base compensation expenses for the quarter increase is 12K to 316K for the 4th quarter of '05 compared to 304K in '04. These costs were related to our pre-IPO stock options. As you know, this treatment will change when we adopt the new FAS 123R as of January 1 of this year.

Our interest income increased approximately $500,000 in the 4th quarter of 2005 compared to 2004 as we earned interest on the cash balances raised during our IPO. For the full year DexCom reported a net loss of 30.8 million for 2005 compared to a net loss of 13.9 million for the full year in 2004. The loss per share was $1.63 for 2005 compared to a loss per share of $7.51 for '04.

Again, those figures are not directly comparable due to the accretion and later conversion of our preferred stock. We did provide a performance disclosure as in the past in the notes to our financial statements that provide additional clarity. So, please refer to our 10K for additional discussion on that.

R&D expense excluding stock based comp for the year increased 13.3 million to 25.5 million for 2005 compared to 12.2 million for 2004. The primary drivers of this increase were again, 7.7 million in higher manufacturing expenses, 3.7 million in higher development expenses, and 1.9 million in higher clinical and regulatory expenses. As we scale our operations in these value added areas after the completion of our pivotal trial and the submittal of our first PMA to the FDA. Included in the higher R&D spending were about 6.4 million in material procurements, most of which hit the 4th quarter as discussed earlier and 3.4 million in high compensation expenses as we continue to build our capabilities, about 1.2 million in tooling and fixturing design costs, and a million dollars in higher clinical and regulatory primarily related to our STS pivotal trial.

As mentioned earlier about 4 million of the materials expenses reflected in our R&D expense are either on hand or on order. As DNA expenses, excluding stock base comp, increased 3.7 million to 5.1 million for the full year of 2005 compared to 1.4 million for 2004. As with the quarter the full year increases are related to initial marketing expenses of about 1.4 million for 2005 where we had none in 2004 and 1.2 million in increased expenses related to operating as a public company.

Our stock based compensation for the year was up a million three to 1.8 million for 2005 compared to 449K in '04. Again, these will change going forward as we implement FAS 123R. Interest income increased approximately 1.5 million for '05 as we invested the proceeds of our IPO and as short-term interest rates continue to rise. We ended 2005 with a very strong balance sheet including 50 million in cash and equivalents so the proceeds from our IPO are essentially sitting in the bank at year end.

Our cash usage from operating activities from the year was about 22.5 million. That includes our 30.7 million dollar loss. So, if you can imagine we had fairly large payables at year end. The annual loss also includes 2.7 million in non-cash charges for a depreciation and amortization. Our cash flow from investing activities other than the purchase and sale of securities related to our cash management program included about 4.7 million in purchases of property, plant and equipment as we significantly increased our manufacturing capacity.

As you know, we continue to believe that our vertical integration here at DexCom allow us to scale very quickly for launch and be able to capture upside demand should it develop. That's it for the prepared financial comments and I will turn it back to Andy Rasdal now for the wrap up.

**MR. RASDAL:**

Thank you, I'd just like to wrap up as we sit here looking into 2006. We're obviously anxiously awaiting a decision from the FDA on the approvability of our short-term sensor STS PMA. In the meantime, we're developing the capabilities to transition from a purely development company into a more commercially focused organization. We've made

substantial progress in preparing our manufacturing of our STS to potentially do that in higher volumes if and when we receive approval. We have hired a very senior experienced sales leader, are busy building a sales marketing customer service organization. Our expanded repeated use trial is giving us wider exposure to a greater number of Diabetes Centers, endocrinologists, diabetes education patients and as a result giving us more experience and feed back related to the product real time.

Still, we continue to keep focused attention on our future pipeline. We understand that to be important to growing a franchise. We still plan to submit regulatory approval of our second generation 7-day STS once we receive an answer regarding the approval of our first PMA. We believe we have a better understanding of a sense of performance and a study design to seek replacement claim labeling from the FDA and intend to file an IDE sometime after we receive a decision of our first STS PMA as well. In the end, we're all real excited and committed to effectively introducing our STS products to people with diabetes if and when we receive approval from the FDA.

So that's the end of the company's prepared comments, we'd be happy to take a couple of questions.

And today's question and answer session will be conducted electronically. You may do so by pressing a star key followed by the digit one. If you've been utilizing your mute button, you want to make sure that is disengaged. Again, star one and we will pause just a moment to assemble the question roster.

Our first question will come from Wade King with Montgomery & Company.

**WADE KING:**

Hi, guys, can you hear me.

**MESSRS. RASDAL AND KEMPFER:**

Yes.

**WADE KING:**

Thanks for the update. A couple of follow-up questions, if I may.

1. You mentioned a couple of things that relates to the buildup of your sales force and the event you get an approvable letter near term. Can you give us any idea in addition to the lead person to head up the sales effort as to the number of sales reps you've hired to date?

**ANSWER:**

Sure, we've, I won't be specific on the numbers we have our sales guy as we indicated, we have hired our first team of regional managers and they are in the process as we said of conducting interviews and finalizing candidate selection.

**WADE KING:**

Okay, maybe I can ask just follow-up related question. Is it a reasonable assumption to figure that you would have up to 20 reps in place to represent the sales force infrastructure by the end of March or early April?

**ANSWER:**

You know it is the timing of FDA approval, if you get approval, always a bit uncertain, it's a bit of a balancing act. As we said previously, it is our intent to be in a position to launch when and if we receive approval with 20-30 people totally in the field, I think that would consist of managers, sales representatives and as we've already spoken about clinical educators and specialists to also help support the product on a technical level.

**WADE KING:**

Okay. Very good. You mentioned a variety of investments that you have made to date as it relates to preparing for production and launch. Could you give us an idea of whether you have actually started to accumulate finish goods at that the company in terms of your production based on all these investments or is that something that is in the hopefully near future.

**ANSWER:**

I think that will probably be a more appropriate comment in the future after we receive approval.

**WADE KING:**

Okay. Very good and last question, please. Thanks for the update on all the activities as it relates to the additional filing you would hope to make assuming you gain approval for the short-term sensor. Can you tell us are there additional claims that you hope to include in a follow-up PMA application for the short-term sensor beyond the increase from 3 to 7-day labeling or are there also additional claims you will be seeking at any follow up application?

**ANSWER:**

Sure, I think we are obviously conducting a study that may include up to 20 centers and 400 patients. There is a good pool of data that may submit, that may support a number of different claims coming out of the things we've been very specific on and probably conducted the feasibility trials as our desire and intention to seek replacement claim labeling from the FDA. We obviously have to get such a study of design approved and conducted successfully. We've always spoken that at some point we would like to seek a clear indication for pediatric under 18 usage as well.

**WADE KING:**

So, once again I appreciate that detail but in the expectation of the almost immediate follow-up to the initial decision from the FDA and the short-term sensor with 3-day labeling when you submitted a follow-up soon there after to that decision, hopefully, will there be additional things other than a 7-day claim that you will be seeking.

**ANSWER:**

Not knowing exactly what the labeling will come out from the FDA at this time, it would just the first filing would support the 7-day.

**WADE KING:**

Okay guys Thanks for the update.

**ANSWER:**

You bet. Our next question comes from Tom Gutterson with Piper Jaffrey.

**TOM GUTTERSON:**

Boy it is all about timing for the FDA isn't it. Wade asked the key questions, I'll just cross those three off and ask my last question and, that is, any discussion between you and the FDA that would help us. Any new news that would help us understand whether or not there is going to be a panel review or not?

**ANSWER:**

Nothing material from us and the FDA would think at this point, we're really just waiting a decision. As we said previously regarding panel, we have not and have not been notified about a need for us to go to panel for this device. But, the FDA only has an obligation to notify you if and when you're going to panel. They do not have an obligation to tell you, you're not going to panel, nor would I expect us to ever hear such a thing, you know, formally. So, we've not been notified to date of the need for that, but again, we cannot formally rule that out.

**TOM GUTTERSON:**

Okay. Thanks. You guys were fast and brief and I will be fast and brief. Thank you.

**ANSWER:**

Thanks, Tom. Our next question is up and enter William Blair.

**WILLIAM BLAIR:**

Good afternoon. Maybe it would be helpful to talk a little bit more about the activities in the 4th quarter on the manufacturing side and you went through that pretty quickly, I think Steve, in the terms of the amount of materials that you guys brought in and how much of that you went through in the 4th quarter and testing versus how much may kind of be in the queue, I think it was 2 million there. Is that right?

**ANSWER (BY STEVE KEMPFER):**

Yes, I can give you a little more information on that piece. Our manufacturing expenses you know for the quarter were 7.7 million higher than in the previous year. The R&D spending included 6.4 million in material procurement, of which about you know 2 million was on hand at the end of the year and 2 million was related to a loss on purchase commitments, that is as materials coming in early part of 2006. So, essentially about 4 million remains out of the 6.4.

**WILLIAM BLAIR:**

Okay, so you went through about 2.4 million in manufacturing increase expense in the 4th quarter. That 2 million related to these, is it electronic components that you don't expect to be using? Were they for the LTS, was that STS?

**ANSWER (BY ANDY RASDAL):**

Yeah, and these are electronic components that we had a commitment on that will support some initial launch quantities for us. We expect as we wrap up our manufacturing operations for those costs to decline rapidly.

**WILLIAM BLAIR:**

Okay, but the 2 million, you said you don't to expect to recover them? Is that the language? There was 2 million components that you didn't expect to utilize early in the launch and you sound like you were writing those off or what was that?

**ANSWER:**

Yeah, it was 2 million of materials that we don't plan on including in our initial pricing with the customer.

**WILLIAM BLAIR:**

I guess that I don't understand what that means and it is probably me, but does that mean that you are not going to be able to sell that eventually, or are your not going to sell it in the time frame you originally thought you'd sell it so and so you have to expense it.

**ANSWER:**

We'll be able to sell, we believe we'll be able to, if we seek approval to sell those components. But like anything initial purchases, especially electrical products maybe a little more expensive upfront. So we expect to be able to recover some portion of those and maybe all of them but the accounting treatment right now, assumes we won't.

**WILLIAM BLAIR:**

Okay, so is like a window in which you had to assume you would be able expense it or to utilize it or otherwise you'd expense it later?

**ANSWER:**

Yes.

**WILLIAM BLAIR:**

Okay, and then, so the increase activities, what can you share with us, what is your current capacity if you had to start selling tomorrow for the STS?

**ANSWER:**

We haven't tried anything related to capacity at this point. You know, if we assume approval, again, it has always been our intention to launch very shortly thereafter and I believe we'd be in a position to do so.

**WILLIAM BLAIR:**

Okay, I don't think I noticed any guidance from you guys for the year, but can you give us any thoughts on what manufacturing expense or R&D expenses, SG&A could be for either the first quarter or the year and I know that depends on the FDA, but just kind of what your take is at this point?

**ANSWER:**

Yes, what were not and are not providing specific financial guidance on revenue expenses. Being in the fourth quarter of '05 we made a level of investments, especially in our materials and/or manufacturer processes that we believe is representative of being ready to support the initial launch of our product should we receive FDA approval. So we expect as we move into the first and second quarter that as we start to scale related to revenues, our operations expenses will become more efficient but that would be offset, initially, at least by additional investment on the sales and marketing side.

**WILLIAM BLAIR:**

Of course. And, last question, Andy in terms of next timing step for FDA, is there a hard deadline that you expect in terms of a reuse cycle, I thought there was a date coming up here shortly for the 180 cycle clock.

**ANSWER:**

There probably is related to the dates but, again, the FDA can keep to their own calendar. So we don't have any exact hard date that we're planning to have a decision on yeah or nay. As you know, we've always guided in general, PMAs take about a year, plus or minus some time frame and that puts us out towards the beginning of Q2 and I think we have been pretty consistent with that in the past but there is no date that we expect they're going to give us an answer one way or the other.

**WILLIAM BLAIR:**

Okay. Thank you.

**RESPONSE:**

Our next question comes from Sarah Michael Moore with Cohen.

**SARAH MICHAEL MOORE:**

Good evening. Thank you. I guess looking a little bit longer term, Andy, I know you want to have about 20-30 support people in the field at launch. But can you give us an idea in terms of just over a 1-2 year period where you see that support side to be to?

**ANDY RASDAL:**

Bigger, I hope. You know, that is always contingent upon, you know, adoption and revenue growth and track of profitability. I think that follows a pretty standard mode, if we get strong traction and the product is what we had hope it is, are able to grow revenues and then we will continue to divide up territories and hire additional reps based upon the need to

better service and drive adoption to new segments of the population. I can't predict what that will be like, as I said, hopefully, much bigger.

**SARAH MICHAEL MOORE:**

Okay, and with 20-30 person field force my guess is that you'd would focus on some of the large centers that, obviously, have big patient numbers and I'm just wondering in the terms of the centers that you target and, how many of those today, could you estimate that you have existing relationships with just from getting clinical trials and some of these other projects that you guys have been working on. How much of a head-start do you have there with some of those influential decision makers.

**ANDY RASDAL:**

Yeah, Yeah, well I think one of the things that certainly changed the last environment from the last 4 or 5 months from our perspective is that we always felt that we always would be a third into the market place and a follower and I think with the status of the two other people playing in that environment, if we receive approval in a timely manner from the FDA we may be the first to really commercially launch a product, is our intention. The thing that changes because of that we are likely to have access to these big centers where we haven't had a presence commercially and as you know the field of continuous is a awful lot of momentum and interest behind it. So, I really think all of the key centers have expressed their interest. We worked in a number of those and I don't know the exact number offhand, so I won't quote it, through clinical studies or discussions with them about appropriate clinical trial designs and so, the biggest thing that has changed is that we have the ability perhaps to get to these big centers fairly early and experience a continuous glucose monitoring and establish DexCom as a foundation for that and get their feedback early and make the required improvements.

**SARAH MICHAEL MOORE:**

Okay, that's helpful and, last would you just on the subject of reimbursement if you could just update us on your thoughts there and what you think the plan would be assuming that you are able to get a timely approval of the product.

**ANDY RASDAL:**

Yeah, sure, I think it is always convenient to build some of the expertise in-house. We've always felt there were a number of things required for reimbursement for the category of continuous glucose monitoring. You know, the first for us will be the approval so that there is significant adoption into the ranks so that we prove that this is useful and reasonably adopted technology so that payers can pay attention and then it's the normal thing, support of advocacy groups. You are probably aware of the JDR initiative related to closed loop systems. The first thing being to get continuous glucose monitors first available which means approved and second accessible which in my mind means reimbursement- and they are putting a lot of their weight and thoughts behind this which is, I think it is for all of us in the category and then to always have good peer reviewed, outcomes related publications, I think we are in a very strong position out with a publication in Diabetes Care. Our first clinical trial we have the data from our 7-day and subsequent trials as we said we submitted to the scientific sections of ACE and ADA and hope for publication and we'll continue to

lend that data related to outcomes for continuous not only to our efforts to seek reimbursement but that can be leveraged by other parties seeking reimbursement as well.

**SARAH MICHAEL MOORE:**

That's very helpful Andy, thank you.

**RESPONSE:**

Our next question is from William Plavanik with First Albany Capital.

**WILLIAM PLAVANIK:**

Great, thank you. Good evening. I think there has been some question out there as to the whole RF signal. Just, my question stems around you got the waive from the FCC on the first generation, is that different with the second generation, do you have to fully redesign the product, that is my first question.

**ANSWER:**

Nope.

**WILLIAM PLAVANIK:**

So then any generation of product you would bring out falls under that waiver?

**ANSWER:**

That is correct. Either the short term or the long term are finable.

**WILLIAM PLAVANIK:**

Fantastic. Secondly, if you look at commercialization of the product, yet compare and contrast which is seen with the player that has received the first approval out there, Medtronic, and kind of what their strategy has been, and what your strategy may be, and how those are different.

**ANSWER:**

I think I only have limited visibility if any to Medtronic Mini-Med's true strategy. It would appear and we can discern that they have launched into a very controlled manner, into a limited small limited numbers of centers to collect data and feedback and move forward. It would be our intention not to limit launch just to a handful of centers. Obviously, we want to work methodically through them but it wouldn't be a matter of just launching through, you know, 10 or so centers and doing that. We're really running our large repeated use trial where it may have up to 20 centers and 400 patients depending on how long it takes to get approval to continue to gain that kind of data and that experience and support reimbursement efforts and so forth on to that data.

**WILLIAM PLAVANIK:**

Great. That is all I had. Thank you very much.

**RESPONSE:**

Our next question comes from Caroline Corner with Montgomery Company.

**CAROLINE CORNER:**

Hi, thanks for taking my question. I have a question first of all about the RF technology. I've taken a look at some of the other diabetes care sites and there is a debate, it seems, between Infer Red and RF communication and with your technology, is it possible to use them on airplanes.

**ANSWER:**

Yes, we believe so and we've tested to quite a number of requirements of interference and so forth with all of regulatory filings.

**CAROLINE CORNER:**

So any kind of interference from airplanes, cell phones, etc. you haven't found anything that would be a problem for diabetics using this system.

**ANSWER:**

Not that we're aware of at this time. Of course, it is one of the reasons that we felt that it was most appropriate for this to file into the next band which is a frequency set aside by the FCC for licenses like this.

**CAROLINE CORNER:**

Okay, great. And then, just a follow-up question about sale force hiring. You said that reps are approaching you to sell the product once you've got approval, have any of the reps coming from other diabetes companies, and if so, are you running into problems with the do-not-compete clauses.

**ANSWER:**

It wouldn't, it wouldn't be appropriate for us to pre-identify folks. But our criteria for hiring people in the field are first and foremost a demonstrable track record of nothing but the highest level of performance not only in the current role but previous ones, strong diabetes related experience. Realizing that with the exception of one company, there is no other commercially marketed continuous glucose monitor so I do not perceive a lot of conflicts as this will be perhaps one of the first of its kind.

**CAROLINE CORNER:**

Okay, great. Thank you for answering my question.

**RESPONSE:**

And as a reminder for initial or follow-up it is star one. We'll next go to Frank Dooter with Eric Gonset.

**FRANK DOOTER:**

Hey guys, quick question on the marketing strategy. Have you guys considered taking this into hospitals for continuous monitoring and also, how can that possibly play a role in getting reimbursement a little quicker.

**ANSWER:**

Sure, yeah we, like probably a number of other people, have read all of the recently rapidly evolving literature on the potential to improve outcomes with people in the hospital by more closely monitoring their glucose. There's some good data obviously related to people both with and without diabetes who may benefit better glycemic control post-operatively or post-traumatically, and, I think we will have more to say in the future but, clearly, that is an opportunity. We see the potential to leverage our platform into the future with that. And second, obviously, anything which shows reductions and length of stay has significant financial impacts and, I think, certainly from an economic standpoint making a faster more understandable argument for reimbursers.

**FRANK DOOTER:**

Have you guys already considered a trial or designed one and, if so, the timing of that?

**ANSWER:**

Yeah, we are. I prefer at this point I won't make any comment about the status of that program, other than to say that we remain highly engaged in that end. I think, that what we have always done at DexCom is, if and when we have successfully conducted a series of trials that we think are meaningful and representative and either us or our clinical investigators, will speak to those as that is the most credible approach.

**FRANK DOOTER:**

Okay, thanks you guys.

**RESPONSE:**

You bet. And with that if there are no further questions, I would like to turn the conference back to Andrew Rasdal for additional or closing remark.

**ANDY RASDAL:**

Okay, thanks we appreciate everybody's attendance and participation today and, as I said earlier we're just anxiously waiting, as Tom noted, a decision from the FDA and, hopefully, in a favorable light being able to get on and hopefully begin to help people suffering from diabetes in earnest with what we hope is an important new intervention for them.

Thanks and good evening.

510559

# EXHIBIT 3

# Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies – for Use by CDRH and Industry

**This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.**

**PMA Staff, Office of Device Evaluation**

**Document issued on: February 19, 1998**

Until May 26, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0079, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After May 26, 1998, comments and suggestions may be submitted at any time for Agency consideration to Kathy M. Poneleit or Lisa C. Fisher, 9200 Corporate Blvd, HFZ-402, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Kathy M. Poneleit or Lisa C. Fisher at 301-594-2186.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies - for Use by CDRH and Industry

## Background/Purpose

The FDA Modernization Act of 1997 (Pub. L. 105-115) added new section 515(d)(3) to the FD&C Act. This section requires FDA, upon written request, to meet with the applicant no later than 100 days after the receipt of a PMA application that has been filed. The purpose of the meeting is to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established. The section also states that, prior to the meeting, FDA is to inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. FDA must also promptly notify the applicant if it identifies additional deficiencies or any additional information required to complete agency review. This guidance[1] describes the procedures to be used to implement this interactive review provision. The guidance applies to original PMA applications received by FDA on or after February 19, 1998. While FDA will honor requests for review status meetings from applicants with pending submissions (i.e., PMA's submitted prior to February 19, 1998), the timing for such meetings will vary depending on the review status of the individual application.

## The Meeting Request

The meeting request should be submitted with the PMA or as an amendment to the PMA no later than 70 days from FDA receipt of the PMA accepted for filing or 70 days from submission of the amendment making the PMA filable ("filing date"). This 30 day lead time is needed to allow FDA sufficient time to schedule the meeting. In the written request, the applicant should specify the type of meeting desired, e.g., face-to-face, teleconference, or videoconference, provide a list of the persons who will attend for the company, and identify several possible dates for the meeting. After a letter filing the application has been issued, the reviewing division will contact the applicant to set up the meeting if requested. As provided by the statute, FDA and the applicant may, by mutual consent, establish a different time for the "day 100" meeting.

## Meeting Preparation and Documentation, Follow-Up

1. There will be identified to the applicant at the time of filing review a contact person on the review team who will ordinarily be the PMA project manager. The person will be responsible for coordinating the project, the interactive review meetings, and status reports.

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2. FDA will provide the applicant with a written description of any deficiencies in the application that, at that point, have been identified based on an interim review of the entire application and will identify the information that is required to correct those deficiencies approximately 90 days from the filing date of the PMA. Minor deficiencies may be identified as well. This early communication will occur whether or not the applicant requests a day 100 meeting. The letter should be faxed to the applicant either by day 90 in the review cycle or at least 10 days prior to any day 100 meeting to facilitate a meaningful dialogue with the applicant.

3. The relevant core review team, Branch Chief, and Division Director or Deputy Director will attend the meeting with the applicant. Others attendees from FDA will include Program Operations Staff (POS) and Office management as appropriate.

4. During the meeting the following may occur:

    - a general discussion of identified issues and discussion of remedial actions,
    - a discussion of an action plan with estimated dates of completion,
    - a discussion of FDA estimated timetables for review completion,
    - identification of the need for panel involvement,
    - a discussion of possible premarket versus postmarket requirements.

5. Draft minutes of the meeting will be distributed to all attendees and the review team leader will provide the final minutes to the attendees, POS, and the administrative record.

6. After the day 100 meeting, FDA will continue to communicate promptly with the applicant via teleconference, fax, videoconference, etc., or in writing the status of the review and what if any additional information has been identified that is required to achieve completion of the review and final action on the application. This continued communication will occur at least every 4 weeks using any of the above methods until the review is completed. Minutes or copies of letters of all such interactions, including teleconferences and videoconferences, will be made a part of the administrative record.